Claims:

1. A method for the treatment of a human patient susceptible to or diagnosed with a disorder characterized by overexpression of ErbB2 receptor, comprising administering an effective amount of an anti-ErbB2 antibody to the human patient, the method comprising:

administering to the patient an initial dose of at least approximately 5 mg/kg of the anti-ErbB2 antibody; and

administering to the patient a plurality of subsequent doses of the antibody in an amount that is approximately the same or less than the initial dose.

2. The method of claim 1, wherein the initial dose is at least approximately 6 mg/kg.

3. The method of claim 2, wherein the initial dose is at least approximately 8 mg/kg.

4. The method of claim 3, wherein the initial dose is at least approximately 12 mg/kg.

5. The method of claim 1, wherein the subsequent doses are separated from each other in time by at least one week.

6. The method of claim 1, wherein the subsequent doses are separated in time from each other by at least two weeks.

7. The method of claim 1, wherein the subsequent doses are separated in time from each other by at least three weeks.

8. The method of claim 1, wherein the initial dose is administered by intravenous injection, and wherein at least one subsequent dose is administered by subcutaneous injection.

9. The method of claim 1, wherein the initial dose is administered by intravenous injection, wherein at least two subsequent doses are administered, and wherein each subsequent dose is administered by a method selected from the group consisting essentially of intravenous injection and subcutaneous injection.

10. The method of claim 1, wherein the initial dose and at least one subsequent dose are administered by subcutaneous injection.

11. The method of claim1, wherein the initial dose is selected from the group consisting essentially of approximately 6 mg/kg, 8 mg/kg, or 12 mg/kg, wherein the plurality of subsequent doses are at least approximately 2 mg/kg, and wherein the subsequent doses are separated in time from each other by at least one week.

12. The method of claim 11, wherein the plurality of subsequent doses are separated in time from each other by at least two weeks.

13. The method of claim 12, wherein the plurality of subsequent doses are separated in time from each other by at least three weeks.

14. The method of claim 13, wherein the initial dose is approximately 8 mg/kg, and wherein at least one subsequent dose is approximately 6 mg/kg.

15. The method of claim 13, wherein the initial dose is approximately12 mg/kg, and wherein at least one subsequent dose is approximately 6 mg/kg.

16. The method of claim 11, wherein the initial dose is approximately 8 mg/kg, and wherein at least one subsequent dose is approximately 8 mg/kg.

17. The method of claim 11, wherein the initial dose is approximately 8 mg/kg, wherein at least one subsequent dose is 8 mg/kg, and wherein administration of the initial dose and subsequent doses are separated in time by at least 2 weeks.

18. The method of claim 17, wherein the initial dose and subsequent doses are separated in time by at least 3 weeks.

19. The method of claim 1, wherein the initial dose is a plurality of doses, wherein each of the plurality of initial doses is at least approximately 1 mg/kg and is administered on at least 2 consecutive days, wherein the at least one subsequent dose is at least approximately 2 mg/kg, and wherein administration of the last initial dose and the first subsequent and additional subsequent doses are separated in time by at least one week.

20. The method of claim 19, wherein the initial dose is a plurality of doses, wherein each of the plurality of initial doses is at least approximately 1 mg/kg and is administered on at least 3 consecutive days, wherein the at least one subsequent dose is at least approximately 6 mg/kg, and wherein administration of the last initial dose and the first subsequent and additional subsequent doses are separated in time by at least 3 weeks.

21. The method of claim 1, wherein the initial dose is a plurality of doses, wherein each of the plurality of initial doses is at least approximately 1 mg/kg and is administered at least twice per week for 3 weeks as a first dosage cycle, wherein the dosage cycle is repeated, and wherein the doses of each cycle are separated in time by at least 1 day, and wherein the dosage cycles are separated in time by at least 1 week.

22. The method of claim 1, wherein said disorder is a benign or malignant tumor.

23. The method of claim 1, wherein said disorder is a cancer.

24. The method of claim 23, wherein said cancer is selected from the group consisting of breast cancer, leukemia, squamous cell cancer, small-cell lung cancer, non-small cell lung cancer, gastrointestinal cancer, pancreatic cancer, glioblastoma, cervical cancer, ovarian cancer, liver cancer, bladder cancer, hepatoma, colon cancer, colorectal cancer, endometrial carcinoma, salivary gland carcinoma, kidney cancer, liver cancer, prostate cancer, vulval cancer, thyroid cancer, hepatic carcinoma and various types of head and neck cancer.

25. The method of claim 24, wherein said cancer is breast cancer.

26. The method of claim 25, wherein said cancer is metastatic breast carcinoma.

27. The method of claim 1 wherein said antibody binds to the extracellular domain of the ErbB2 receptor.

28. The method of claim 27, wherein said antibody binds to epitope 4D5 within the ErbB2 extracellular domain sequence.

29. The method of claim 28, wherein said antibody is a humanized 4D5 anti-ErbB2 antibody.

30. The method of claim 1 wherein the method further comprises administering an effective amount of a chemotherapeutic agent.

31. The method of claim 30, wherein the chemotherapeutic agent is a taxoid.

32. The method of claim 31, wherein said taxoid is paclitaxel or docetaxel.

33. The method of claim 30, wherein the effective amount of the anti-ErbB2 antibody and the effective amount of the chemotherapeutic agent as a combination is lower than the sum of the effective amounts of said anti-ErbB2 antibody and said chemotherapeutic agent, when administered individually, as single agents.

34. The method of claim 30, wherein the chemotherapeutic agent is an anthrcycline derivative.

35. The method of claim 34, wherein the anthracycline derivative is doxorubicin or epirubicin.

36. The method of claim 34, wherein the method further comprises administration of a cardioprotectant.

37. The method of claim 1, wherein efficacy is measured by determining the time to disease progression or the response rate.

38. An article of manufacture, comprising a container, a composition within the container comprising an anti-ErbB2 antibody, and a package insert containing instructions to administer an initial dose of anti-ErbB2 antibody of at least 5 mg/kg, and at least one subsequent dose that is the same amount or less than the initial dose.

39. The article of manufacture of claim 38, wherein the instructions are for administration of an initial dose by intravenous injection and at least one subsequent dose by subcutaneous injection.

40. The article of manufacture of claim 38, wherein the initial dose is at least approximately 6 mg/kg.

41. The article of manufacture of claim 40, wherein the initial dose is at least approximately 8 mg/kg.

42. The article of manufacture of claim 41, wherein the initial dose is at least approximately 12 mg/kg.

43. The article of manufacture of claim 38, wherein the subsequent doses are separated from each other in time by at least one week.

44. The article of manufacture of claim 38, wherein the subsequent doses are separated in time from each other by at least two weeks.

45. The article of manufacture of claim 38, wherein the subsequent doses are separated in time from each other by at least three weeks.

46. The article of manufacture of claim 38, wherein the initial dose and at least one subsequent dose are administered by subcutaneous injection.

47. The article of manufacture of claim 38, wherein the initial dose is selected from the group consisting essentially of approximately 6 mg/kg, 8 mg/kg, or 12 mg/kg, wherein the plurality of subsequent doses are at least approximately 2 mg/kg, and wherein the subsequent doses are separated in time from each other by at least one week.

48. The article of manufacture of claim 47, wherein the plurality of subsequent doses are separated in time from each other by at least two weeks.

49. The article of manufacture of claim 48, wherein the plurality of subsequent doses are separated in time from each other by at least three weeks.

50. The article of manufacture of claim 49, wherein the initial dose is approximately 8 mg/kg, and wherein at least one subsequent dose is approximately 6 mg/kg.

51. The article of manufacture of claim 49, wherein the initial dose is approximately12 mg/kg, and wherein at least one subsequent dose is approximately 6 mg/kg.

52. The article of manufacture of claim 47, wherein the initial dose is approximately 8 mg/kg, and wherein at least one subsequent dose is approximately 8 mg/kg.

53. The article of manufacture of claim 47, wherein the initial dose is approximately 8 mg/kg, wherein at least one subsequent dose is 8 mg/kg, and wherein administration of the initial dose and subsequent doses are separated in time by at least 2 weeks.

54. The article of manufacture of claim 53, wherein the initial dose and subsequent doses are separated in time by at least 3 weeks.

55. The article of manufacture of claim 38, wherein the initial dose is a plurality of doses, wherein each of the plurality of initial doses is at least approximately 1 mg/kg and is administered on at least 2 consecutive days, wherein at least one subsequent dose is at least approximately 2 mg/kg, and wherein administration of the last initial dose and the first subsequent and additional subsequent doses are separated in time by at least one week.

56. The article of manufacture of claim 55, wherein the initial dose is a plurality of doses, wherein each of the plurality of initial doses is at least approximately 1 mg/kg and is administered on at least 3 consecutive days, wherein the at least one subsequent dose is at least approximately 6 mg/kg, and wherein administration of the last initial dose and the first subsequent and additional subsequent doses are separated in time by at least 3 weeks.

57. The article of manufacture of claim 38, wherein the initial dose is a plurality of doses, wherein each of the plurality of initial doses is at least approximately 1 mg/kg and is administered at least twice per week for 3 weeks as a first dosage cycle, wherein the dosage cycle is repeated, and wherein the doses of each cycle are separated in time by at least 1 day, and wherein the dosage cycles are separated in time by at least 1 week.

58. The article of manufacture of claim 38, wherein the instructions are for administration of an initial dose by subcutaneous injection and at least one subsequent dose by subcutaneous injection.

59. The article of manufacture of claim 58, wherein the initial dose is at least approximately 6 mg/kg.

60. The article of manufacture of claim 59, wherein the initial dose is at least approximately 8 mg/kg.

61. The article of manufacture of claim 60, wherein the initial dose is at least approximately 12 mg/kg.

62. The article of manufacture of claim 58, wherein the subsequent doses are separated from each other in time by at least one week.

63. The article of manufacture of claim 58, wherein the subsequent doses are separated in time from each other by at least two weeks.

64. The article of manufacture of claim 58, wherein the subsequent doses are separated in time from each other by at least three weeks.

65. The article of manufacture of claim 58, wherein the initial dose is selected from the group consisting essentially of approximately 6 mg/kg, 8 mg/kg, or 12 mg/kg, wherein the plurality of subsequent doses are at least approximately 2 mg/kg, and wherein the subsequent doses are separated in time from each other by at least one week.

66. The article of manufacture of claim 58, wherein the plurality of subsequent doses are separated in time from each other by at least two weeks.

67. The article of manufacture of claim 66, wherein the plurality of subsequent doses are separated in time from each other by at least three weeks.

68. The article of manufacture of claim 67, wherein the initial dose is approximately 8 mg/kg, and wherein at least one subsequent dose is approximately 6 mg/kg.

69. The article of manufacture of claim 67, wherein the initial dose is approximately12 mg/kg, and wherein at least one subsequent dose is approximately 6 mg/kg.

70. The article of manufacture of claim 65, wherein the initial dose is approximately 8 mg/kg, and wherein at least one subsequent dose is approximately 8 mg/kg.

71. The article of manufacture of claim 65, wherein the initial dose is approximately 8 mg/kg, wherein at least one subsequent dose is 8 mg/kg, and wherein administration of the initial dose and subsequent doses are separated in time by at least 2 weeks.

72. The article of manufacture of claim 71, wherein the initial dose and subsequent doses are separated in time by at least 3 weeks.

73. The article of manufacture of claim 58, wherein the initial dose is a plurality of doses, wherein each of the plurality of initial doses is at least approximately 1 mg/kg and is administered on at least 2 consecutive days,

wherein at least one subsequent dose is at least approximately 2 mg/kg, and wherein administration of the last initial dose and the first subsequent and additional subsequent doses are separated in time by at least one week.

74. The article of manufacture of claim 73, wherein the initial dose is a plurality of doses, wherein each of the plurality of initial doses is at least approximately 1 mg/kg and is administered on at least 3 consecutive days, wherein the at least one subsequent dose is at least approximately 6 mg/kg, and wherein administration of the last initial dose and the first subsequent and additional subsequent doses are separated in time by at least 3 weeks.

75. The article of manufacture of claim 58, wherein the initial dose is a plurality of doses, wherein each of the plurality of initial doses is at least approximately 1 mg/kg and is administered at least twice per week for 3 weeks as a first dosage cycle, wherein the dosage cycle is repeated, and wherein the doses of each cycle are separated in time by at least 1 day, and wherein the dosage cycles are separated in time by at least 1 week.

76. The article of manufacture of claim 38, wherein the instructions further include administration of a chemotherapeutic agent.

77. The article of manufacture of claim 76, wherein the chemotherapeutic agent is a taxoid.

78. The article of manufacture of claim 77, wherein the taxoid is paclitaxel or docetaxel.

79. The article of manufacture of claim 76, wherein the chemotherapeutic agent is an anthracycline derivative.

80. The article of manufacture of claim 79, wherein the instructions further include administration of a cardioprotectant.

81. The article of manufacture of claim 38, further comprising a label on or associated with the container that indicates that said composition can be used for treating a condition characterized by overexpression of ErbB2 receptor.

82. The article of manufacture of claim 81, wherein said label indicates that said composition can be used for the treatment of breast cancer.

83. The article of manufacture of claim 38, wherein said anti-ErbB2 antibody binds to the extracellular domain of the receptor.

84. The article of manufacture of claim 83, wherein said anti-ErbB2 antibody binds to epitope 4D5 within the ErbB2 extracellular domain sequence.

85. The article of manufacture of claim 84, wherein said antibody is a humanized 4D5 anti-ErbB2 antibody.

86. A method for the treatment of cancer in a human patient comprising administering to the patient a first dose of an anti-ErbB2 antibody followed by at least one subsequent dose of the antibody, wherein the first dose and subsequent dose are separated from each other in time by at least about two weeks.

87. The method of claim 86, wherein the first dose and subsequent dose are separated from each other in time by at least about three weeks.

88. The method of claim 86, wherein the first dose and subsequent dose are each from about 2mg/kg to about 16mg/kg.

89. The method of claim 88, wherein the first dose and subsequent dose are each from about 4mg/kg to about 12mg/kg.

90. The method of claim 89, wherein the first dose and subsequent dose are each from about 6mg/kg to about 12mg/kg.

91. The method of claim 86, wherein two or more subsequent doses of the antibody are administered to the patient.

92. The method of claim 91, wherein from about two to about ten subsequent doses of the antibody are administered to the patient.

93. The method of claim 91, wherein the two or more subsequent doses are separated from each other in time by at least about two weeks.

94. The method of claim 93, wherein the two or more subsequent doses are separated from each other in time by at least about three weeks.

95. The method of claim 91, wherein the two or more subsequent doses are each from about 2mg/kg to about 16mg/kg.

96. The method of claim 91, wherein the two or more subsequent doses are each from about 4mg/kg to about 12mg/kg.

97. The method of claim 91, wherein the two or more subsequent doses are each from about 6mg/kg to about 12mg/kg.

98. The method of claim 86, wherein the method further comprises administering an effective amount of a chemotherapeutic agent to the patient.

99. The method of claim 98, wherein the chemotherapeutic agent is a taxoid.

100. An article of manufacture, comprising a container, a composition within the container comprising an anti-ErbB2 antibody, and a package insert containing instructions to dose the antibody according to any one of claims 86 to 99.

101. A method for the treatment of cancer in a human patient, comprising administering an effective amount of an anti-ErbB antibody to the human patient, the method comprising:
administering to the patient an initial dose of at least approximately 5 mg/kg of the anti-ErbB antibody; and administering to the patient a plurality of subsequent doses of the antibody in an amount that is approximately the same or less than the initial dose.

102. The method of claim 101 wherein the anti-ErbB antibody is selected from the group consisting of anti-epidermal growth factor receptor (EGFR), anti-ErbB3 and anti-ErbB4.

103. A method for the treatment of cancer in a human patient comprising administering to the patient a first dose of an anti-ErbB antibody followed by at least one subsequent dose of the antibody, wherein the first dose and subsequent dose are separated from each other in time by at least about two weeks.

104. The method of claim 103 wherein the anti-ErbB antibody is selected from the group consisting of anti-epidermal growth factor receptor (EGFR), anti-ErbB3 and anti-ErbB4.

105. An article of manufacture, comprising a container, a composition within the container comprising an anti-ErbB antibody, and a package insert containing instructions to dose the antibody according to any one of claims 101 to 104.